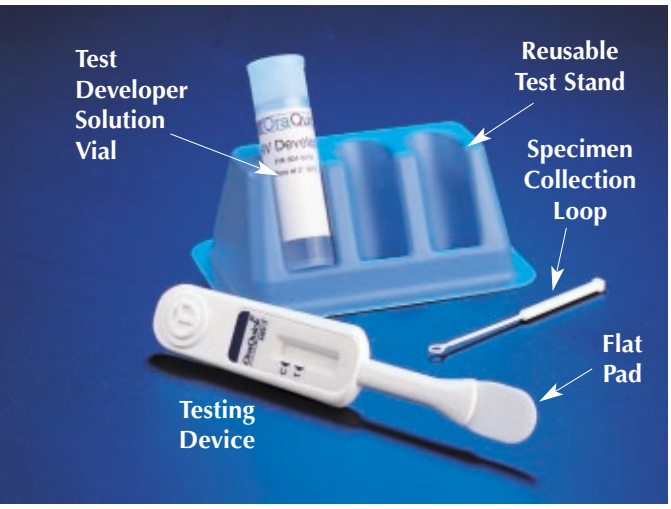
OraQuick®
Rapid HIV-1 Antibody Test

Step-by-Step Instructions for OraQuick® Rapid HIV-1 Antibody Test



Materials Supplied:

The OraQuick® Rapid HIV-1 Antibody Test consists of:

- A single-use testing device,
- A single-use test developer solution vial,
- A reusable test stand, and
- Disposable single-use specimen collection loops.

In addition, you will need to have a timer or watch for timing the 20 to 40 minute test development time. You will also need appropriate lighting to read test result.

Other items that may be needed:

- Standard materials for collection of blood from the finger (e.g., lancet, antiseptic wipe, sterile gauze pad).
- Standard materials for collection of blood from the vein.

Please note:

Handle all specimens and materials contacting specimens as infectious waste.[1]

[1] See "Universal Precautions," CDC, MMWR, June 24, 1988.

For Investigational Use Only
The performance characteristics of this product have not been established.

GENERAL INFORMATION

Please read these instructions completely before performing testing. Not doing so may result in inaccurate test results.

General Test Preparations

- Place the test stand on a flat level surface. Use only the stand provided.
- Using the notched corners, tear the top of each side of the divided pouch containing the testing device and vial of developer solution.
- To prevent contamination, leave the testing device in its pouch until needed. DO NOT touch the flat pad.
- Remove the vial of developer solution.
- Firmly holding the vial, carefully uncap the vial by gently rocking the cap back and forth.
- Slide the uncapped vial into the angled stand making sure the vial is completely seated in the stand. **DO NOT** snap the vial into the stand as splashing may occur.
- **DO NOT** cover the two holes on the back of the testing device. Doing so may cause an invalid result.

Quality Control

OraQuick HIV-1 Kit Controls are supplied separately.

- Read the OraQuick HIV-1 Kit Controls Package Insert before proceeding. Not doing so may result in inaccurate test results.
- The Kit Controls verify that the test is working properly. Persons administering and reading OraQuick Rapid HIV-1 Antibody Tests **MUST** run these Kit Controls once per shift AND whenever there is a change to a different lot number of tests.
- If the results of the control tests match the expected results, proceed with specimen testing.
- If the results of the control tests **DO NOT MATCH** the expected results, repeat testing of the Kit Control panel using additional OraQuick Rapid HIV-1 Antibody Tests.
- If the results of the repeated tests match the expected results, proceed with patient specimen testing. If the results of the repeated tests **DO NOT MATCH** the expected results, call OraSure Technologies Customer Service for technical assistance.
- Use the Quality Control tests to help you find good lighting. If you cannot easily see the bands that develop on the Positive Control, vary the lighting conditions until you find light that allows you to see the bands. Then use these same conditions when reading patient results.

Step-by-Step Instructions for OraQuick® Rapid HIV-1 Antibody Test Sample Collection & Testing Procedures

Please note: You can choose to run the test using any of the following specimens:

Oral Fluid Test

Step 1

Have the person being tested remove the testing device from its pouch. Direct the person to place the flat pad above their teeth against their outer gum. Direct the person to gently swab completely around the outer gums, both upper and lower, one time around, using the flat part of the pad. DO NOT allow the person to swab the roof of their mouth, the inside of their cheek or their tongue. **NOTE:** It is okay to use *both* sides of the pad during this procedure. (Refer to the pictures on the left to help you show the person how to collect the specimen.)

Step 2

Take the testing device from the person. Insert the testing device, flat pad first, into the test developer solution vial. Be sure that the results window faces forward and the flat pad touches the bottom of the vial.

Step 3

Leave the device in the vial and start timing the test. Do not remove the device from the vial until you are done reading the results. Read the results after 20 minutes. Do not exceed 40 minutes.

Turn to the Reading Test Results section of these instructions. Read and record the test results.

After recording the results, dispose of used testing materials in accordance with local regulations for infectious waste.

Fingerstick Blood Test

Step 1

Clean the finger of the person being tested with an antiseptic wipe. Allow the finger to dry thoroughly or wipe dry with a sterile gauze pad. Use a lancet to puncture finger. Allow a drop of blood to form.

Step 2

Use a new specimen collection loop each time you perform the test. Touch the round end of the loop to the blood. Visually inspect the loop to make sure that it is completely filled with blood.


Step 3

Put the blood-filled loop into the developer solution inside the vial. Use the loop to stir the specimen in the developer solution. Solution will appear pink if the blood specimen was properly introduced. Remove the disposable loop and discard as infectious waste.

Step 4

Remove the testing device from its pouch. Insert the testing device, flat pad first, into the test developer solution vial containing the specimen. Be sure that the results window faces forward and the flat pad touches the bottom of the vial.


Step 5

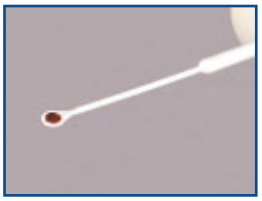
Leave the device in the vial and start timing the test. Do not remove the device from the vial until you are done reading the results. Read the results after 20 minutes. Do not exceed 40 minutes.

Turn to the Reading Test Results section of these instructions. Read and record the test results.

After recording the results, dispose of used testing materials in accordance with local regulations for infectious waste.

Whole Blood Test

Please note: You may use this same procedure for plasma/serum specimens.

Step 1

Thoroughly mix the tube of whole blood. Uncap the tube. Touch the collection loop to the blood specimen. Visually inspect the loop to make sure that it is completely filled with a specimen. You may use a 5 microliter pipette instead of the disposable loop.


Step 2

Put the blood-filled loop into the developer solution inside the vial. Use the loop to stir the specimen in the developer solution. Solution will appear pink if the blood specimen was properly introduced. Remove the disposable loop and discard as infectious waste.

Step 3

Remove the testing device from its pouch. Insert the testing device, flat pad first, into the test developer solution vial containing the specimen. Be sure that the results window faces forward and the flat pad touches the bottom of the vial.


Step 4

Leave the device in the vial and start timing the test. Do not remove the device from the vial until you are done reading the results. Read the results after 20 minutes. Do not exceed 40 minutes.

Turn to the Reading Test Results section of these instructions. Read and record the test results.

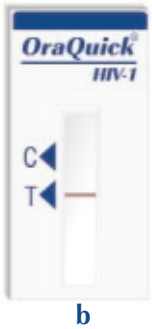
After recording the results, dispose of used testing materials in accordance with local regulations for infectious waste.

READING RESULTS

Reading Test Results

APPROPRIATE LIGHTING REQUIRED

a



b

c

Reading an INVALID result:

- No line appears in the control (C) area, indicating that the test did not function properly (examples a & b).
- If the line is not touching any part of the blue triangle, the test is invalid (example c).
- Record the result as Invalid.

For an INVALID result:

- With an oral fluid specimen, the test should be performed again with a new device using a blood specimen.
- With a blood specimen, the test should be performed again using a new device and blood specimen.
- If a second test should fail, contact OraSure Technologies Customer Service for technical assistance.

Reading a NEGATIVE result:

- Only the control (C) area shows a line, and No line is present in the test (T) area.
- A negative result suggests an absence of HIV antibodies in the specimen.
- Record the result as Negative.

For a NEGATIVE result:

Refer to CDC or WHO Guidelines for appropriate counseling messages.

Reading a REACTIVE result:

- Lines appear in both the control (C) and test (T) areas. Even a very faint test (T) band should be read as reactive.
- One line may appear lighter or less consistent than the other.
- A reactive result suggests the presence of HIV antibodies in the specimen.
- Record the result as Reactive.

For a REACTIVE result:

Refer to CDC or WHO Guidelines for appropriate counseling messages.

- A supplemental test to confirm results will need to be performed.

NOTE:

If at 20 minutes:

- a red background in the results window makes it difficult to read the results and/or,
- the control line is not visible, then wait to read the results up to 40 minutes total time. (*Occasionally lines at the "T" section may develop on otherwise negative devices after 40 minutes. These late-developing lines do not reflect a correct result and should be disregarded.)*

OraSure Technologies, Inc.

diagnostic solutions for the new millennium

For answers to questions regarding the OraQuick® Rapid HIV-1 Antibody Test
or for more information on other
OraSure Technologies' products, call:
1-800-869-3538 or visit our web site: www.orasure.com

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L3001-0644 (rev. 05/02)